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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,275	08/22/2001	Gerardo Castillo	PROTEO.P03	1974

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,275	CASTILLO ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11,12,15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11,12,15 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/24* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 11, 12 and 15 have been amended, claims 6-10, 13, 14 and 16 have been cancelled and claims 19-21 have been added as requested in the amendment of Paper filed on November 24, 2003. Claims 1-5, 11, 12, 15 and 17-21 are pending in the instant application.

Claims 1-5, 11, 12, 15 and 17-21 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on November 24, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 1-5, 11, 12, 15, 17, 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 3 of Paper No. 12.

Applicant traverses the rejection on the premises that "Applicant did in fact reasonably so predict *in vivo* success based on demonstrated *in vitro* results, and these predictions have since been borne out, both in further laboratory testing of animals and in subsequent studies by colleagues" (bottom at page 6 of the Response). Applicant further describes the positive results

of *in vivo* experiments obtained from mice intracranially infused with laminin. Applicant also submits two post-filing date publications describing inhibitory effect of laminin on Aβ fibrils formation. These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The essential disagreement appears to be the issue of predictability of the *in vitro* experiments establishing the ability of laminin or specific fragments thereof to inhibit formation of amyloid fibrils and *in vivo* treatment of Alzheimer's disease by administration of "a polypeptide having a conformational similarity to a fragment of a laminin protein". The Examiner maintains the position that the instant specification, as filed, is not enabled for the claimed method of treatment of Alzheimer's disease. The specification provides limited information regarding *in vitro* data of inhibition Aβ aggregation by laminin and an assertion that laminin or its fragments if administered to a patient suffering from a beta-amyloid protein disease would inhibit formation, deposition or accumulation of amyloid fibrils, such assertion not supported by any facts of record. Because at the time of invention effectiveness of laminin treatment of Alzheimer's disease has not been established, a skilled practitioner would have to solely rely on the instant specification to practice the claimed method, and the instant disclosure clearly fails to provide enough guidance on how to carry the instant method without undue experimentation. For the same reasons, any subsequently presented data cannot serve as supporting non-enabling originally filed disclosure. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

Furthermore, even if to accept Applicant's submission of data obtained on mice treated with laminin or laminin fragments, it appears that such treatment is only established for intracranial administration of laminin, while the instant claims are currently broadly drawn a method of treatment by administration of "a polypeptide having a conformational similarity to a fragment of a laminin protein" in general.

Applicant's arguments that "the law does not require that the art already have established such a direct correlation [of *in vitro* and *in vivo* results]... In this case, it turns out it was entirely and imminently reasonable to predict that the demonstrated *in vitro* results would predict the success of *in vivo* results, because that is just what happened" (bottom at page 6 of the Response) are not persuasive because the instant invention relates to the field of treatment of Alzheimer's disease, for which no current treatment is currently available or, in other words, an unpredictable

scientific area. Therefore, in view of the absence of working examples related to the claimed *in vivo* treatment or any strong scientific evidence establishing the predictability of *in vitro* results, no direct extrapolation can be made of the data disclosed in the instant specification to a method of treatment of Alzheimer's disease. See also *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970), which held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved".

Contrary to Applicant's statement that "[s]uch practice would NOT require any knowledge of route, duration or quantity in advance of reading the specification because [...] all that information is readily available to one skilled in the art upon appreciation of the specification" (first paragraph at page 9 of the Response), such information is not readily

available because it is absent for the specification and is not obvious from prior art. In view of art recognition of the absence of treatment of Alzheimer's disease and total lack of guidance or working examples on how to establish a therapeutically effective dose of "a polypeptide having a conformational similarity to a fragment of a laminin protein", how to determine "conformational similarity to a fragment of a laminin protein" in general and the level of 70% or 90% of similarity in particular, or the regime of administration of such polypeptide, it can be concluded that the instant specification is not enabling for the claimed method and that it would require a substantial amount of undue experimentation in order to practice the instant invention, as currently claimed.

6. Claims 1-4 stand indefinite for recitation "conformational similarity" for reasons of record in section 7 of Paper No. 12. Applicant's arguments that "conformation" and "conformational similarity" are well defined in the specification (at page 53 for instance)" (middle at page 10 of the Response) are not persuasive because there appears to be no disclosure presented in the instant specification, including page 53, that would clearly describe the distinguishing features of "conformational similarity", physical or chemical characteristics associated with conformation, identification of structure to be conserved or modified to meet the instant limitation. Further, because the instant specification fails to teach how to determine percent of conformational similarity (see reasoning in section 5 of the instant office action), the metes and bounds of the recitation "70%" or "90%" conformational similarity remain vague and obscure.

7. Claims 1, 15, 17 and 18 stand rejected for being indefinite for reasons of record in section 8 of Paper No. 12. Without stating an objective what the amount of a polypeptide is effective for and what therapeutic effect is achieved the claimed subject matter remains indefinite.

8. Claims 5, 11, 12 and 20 are indefinite for being dependent form indefinite claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 19 is vague and ambiguous for recitation of "an environment". This term is very broad and generally defined as "conditions under which one lives". Although MPEP specifically expresses that claim breadth should not be equated with indefiniteness (MPEP 2173.04), in the instant situation, the breadth of the term "an environment" makes the claimed subject matter indecipherable.

During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Because the instant specification does not define "an environment" and the broadest possible interpretation allows an assertion that a method implies treatment of "conditions under which one lives", the claim, as written, is considered vague and indefinite.

11. Claim 21 is indefinite for being dependent from indefinite claim.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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